

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: FOSAMAX (ALENDRONATE
SODIUM): PRODUCTS LIABILITY
LITIGATION**

THIS DOCUMENT RELATES TO:

Zessin et al., v. Merck Sharp & Dohme Corp.

Civil Action No. 11-cv-3918 (JAP)(LHG)

Young v. Merck Sharp & Dohme Corp.

Civil Action No. 11-cv-3225 (JAP)(LHG)

Johnson v. Merck Sharp & Dohme Corp.

Civil Action No. 11-cv-5301 (JAP)(LHG)

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Civil No. 11-cv-3225 (JAP)(LHG)

Civil No. 11-cv-5301 (JAP)(LHG)

**DEFENDANT MERCK SHARP & DOHME CORP.'S
MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION
TO STRIKE DR. ROBERT MAKUCH FROM PLAINTIFFS' RULE 26(a)(2)
DISCLOSURE AND EXCLUDE HIS TESTIMONY AT TRIAL**

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INTRODUCTION

Pursuant to Federal Rules of Civil Procedure 26 and 37, Defendant Merck Sharp & Dohme Corp. (“Merck”) moves to strike Dr. Robert Makuch from the Federal Rule of Civil Procedure 26(a)(2) Statement served by Plaintiff Deloris Zessin on April 1, 2013 (*see* Declaration of Karen A. Confoy, (“Confoy Dec.”) Exh. 1, Plaintiffs’ Rule 26(a) Disclosure, Apr. 1, 2013) and to exclude his testimony and references to his opinions at trial. Plaintiff’s disclosure of the general causation opinions of Dr. Makuch is clearly untimely. Allowing Plaintiff’s tardy disclosure months after Merck disclosed its general causation experts, and months after Merck deposed Plaintiff’s timely disclosed experts would prejudice Merck and further would waste the time and resources of the parties and the Court. Plaintiffs should not be permitted to jettison their initial general cause experts, Drs. Klein and Cornell, and replace them with a different expert disclosed nearly six months after the deadline. Neither the Court’s Case Management Orders (“CMOs”) nor the Federal Rules allow Plaintiffs a do-over on their general causation expert disclosures.

LEGAL ARGUMENT

- A. Under this Court's Case Management Orders, Plaintiffs in The First Four Bellwether Trials Were Required to Disclose General Causation Experts on October 15, 2012.

On July 14, 2011 and November 14, 2012, this Court signed and put into place CMO 4 and CMO 4A, respectively, which set forth the pretrial schedule for the "Early Trial Cases." The "Early Trial Cases" included four cases: *Glynn*, *Zessin*, *Young*, and *Soudelier* (subsequently replaced by *Johnson* after Plaintiffs dismissed *Soudelier*). The plain language of CMO 4A makes clear that the deadlines for the parties' Rule 26(a)(2) disclosures and expert depositions set forth in paragraph four apply to general causation experts for all four of the Early Trial Cases as well as all case-specific experts in the *Glynn* case. Compare Confoy Dec. Exh. 2, CMO 4A ¶ 4(A) ("Expert discovery on general causation (i.e. whether Fosamax or alendronate can be a cause of femur fractures), as well as all expert discovery in the *Glynn* case, shall be completed by January 11, 2013 in accordance with the following schedule") (emphasis added) with CMO 4A ¶ 5(A) ("Expert discovery in the *Zessin* case, shall be completed by June 3, 2013 in accordance with the following schedule") and CMO 4A ¶ 6(A) ("Expert discovery in the *Young* case, shall be completed by January 11, 2013 in accordance with the following schedule"). Notably, because the Court required expert discovery on general causation to be completed prior to the start of the *Glynn* trial for the four

Early Trial Cases that will be tried in quick succession, the paragraphs of CMO 4A dealing with deadlines for case-specific experts in the *Zessin* and *Young* cases do not include deadlines for disclosure of general causation experts. Those deadlines expired for Plaintiffs on October 15, 2012 and Merck on November 13, 2012. *Id.*

The Court's CMOs sensibly set forth an orderly procedure whereby Plaintiffs in the Early Trial Cases disclosed all their general cause experts, Merck responded with its general causation experts, and the Court addressed *Daubert* concerns at a single time. Merck believed this was in fact done when, on October 15, 2012, Plaintiffs served general causation expert reports for Dr. Cheryl Blume, Dr. David Madigan, Dr. Charles Cornell, and Dr. Michael Klein, which were followed by Merck serving its Rule 26(a)(2) disclosure for general causation experts and *Glynn* case-specific experts on November 13, 2012. *See* Confoy Dec.Exh. 3, Statement of Defendant Merck Sharp & Dohme Corp. Pursuant to Federal Rule of Civil Procedure 26(a)(2), Nov. 13, 2012).¹

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1. The PSC recognizes the difference between general experts in the MDL, for which disclosure was required prior to commencement of the *Glynn* trial, from those designated for specific cases. For example, when arguing that Dr. Blume should not be questioned about monies made for her work on the general cases in the MDL, counsel for Plaintiff stated "[a]s the Court may be aware, I know the defendants are, Dr. Blume was prepared as a general expert by the plaintiffs' steering committee here in the MDL for the entirety of the litigation. A great deal of her work, therefore, was generally applicable to I guess about 1000 cases, not to mention she's also designated generally in the New Jersey

It was never contemplated by the parties nor allowed for by the Court's CMOs that the parties would engage in multiple rounds of general causation expert disclosures and general causation *Daubert* briefing in the Early Trial Cases.² Serial general causation expert discovery not only is inefficient for the Court and the parties, it is particularly prejudicial to Merck as it would afford Plaintiffs three opportunities for de facto unauthorized rebuttal reports. As discussed below, this potential prejudice is not just theoretical but in fact has played out in the *Zessin* case.

B. Plaintiff Zessin's Disclosure of Dr. Makuch is Untimely and Should Be Excluded.

On April 1, 2013, almost six months after the deadline for disclosure of general causation experts passed, Plaintiffs disclosed a new general causation expert – Dr. Robert W. Makuch – in their *Zessin* case specific expert disclosure. As Dr. Makuch explains in his report, he was asked to write a report to “delineate

state court, so there are thousands of cases for which she prepared the general report.” Confoy Dec. Exh. 4, *Glynn* Trial Tr. at 539:21-540:4, Apr. 11, 2013.

2. When the Court expressed concern with the “truckloads” of briefing that had been submitted by both sides prior to the *Glynn* trial, and expressed specific concern that it not “be given the volume of motions before [subsequent bellwether] cases get started because it’s simply impossible to deal with” PSC counsel represented that the first MDL bellwether trial is “when the freight train goes through of motion practice and all of this is decided basically once and then doesn’t have to be addressed again.” Confoy Dec. Exh. 5, *Glynn* Pre-Trial Hr’g Tr. at 4:9-5:9, Feb. 21, 2013. Obviously, if *Daubert* is to be redone as both sides act and react to each side’s new general expert disclosures, this would not be the case.

the risk of atypical subtrochanteric and diaphyseal fractures linked to bisphosphonate therapy, and in doing so, assess this aggregated evidence to establish, within a reasonable degree of scientific certainty, whether or not bisphosphonates are a significant contributing factor to atypical femoral fractures.” Confoy Dec. Exh. 6, Makuch Report at 4, Mar. 29, 2013. At the conclusion of Dr. Makuch’s report, he offers the following opinion: “I have reviewed literature that reports a range of risk found by various authors, but regardless the range in magnitude, population-based data in the medical literature support the assertion that there is a strong cause-effect association of increased risk of atypical femoral fractures with bisphosphonate use.” *Id.* at 32. Dr. Makuch’s report does not contain any case-specific opinions with respect to Plaintiff Zessin (or any other plaintiff). As such, Dr. Makuch discloses purely general causation opinions that were required to be disclosed pursuant to CMO 4A on October 15, 2012.³

Plaintiffs’ disclosure of a general causation expert six months after the deadline set by this Court in CMO 4A is a clear violation of Federal Rule of Civil Procedure 26(a)(2), which provides that “the parties must disclose their experts and

3. As part of their expert disclosures in *Zessin*, Plaintiffs also disclosed Dr. Anthony Mechrefe. Dr. Mechrefe includes case-specific opinions relating to the *Zessin* case in addition to general cause opinions. Since Dr. Mechrefe’s general causation opinions relate to his timely disclosed case-specific opinions, Merck is not seeking to exclude his opinions here. Plaintiff Zessin also incorporated the general reports served previously by Drs. Blume and Madigan, but not Drs. Klein and Cornell.

the contents of their reports within the time frame set by the Court.” *Roberts v. United States*, CIV.A. 09-6212 WJM, 2012 WL 2374656, at *3 (D.N.J. June 22, 2012). A “failure to comply with the disclosure requirements of the Rule frustrates the purpose of the Rules – the elimination of unfair surprise and the conservation of resources.” *D & D Assoc., Inc. v. N. Plainfield Bd. of Ed.*, 2006 WL 1644742, at *3 (D.N.J.2006). Thus, when a party fails to make the required disclosures in the time frame set forth by the court and as required by Rule 26 (a) or (e), “the party is not allowed to use that information or witness to supply evidence...unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1).

Here, Plaintiffs failed to disclose Dr. Makuch in accordance with the requirements of CMO 4A and such failure is neither substantially justified nor harmless. “The party who has failed to disclose information bears the burden to show that the nondisclosure was substantially justified or is harmless.” *D & D Assoc., Inc.*, 2006 WL 1644742, at *3. *Accord Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div.*, 60 F.3d 153, 156 (3d Cir. 1995) (“Rule 37 is written in mandatory terms, and is designed to provide a strong inducement for disclosure of Rule 26(a) material.”). “Substantial justification requires justification to a degree that could satisfy a reasonable person that parties could differ as to whether the party was required to comply with the disclosure request. The proponent’s

position must have a reasonable basis in law and fact.” *Id.* at *4 (citations omitted).

“Factors to consider when determining whether a failure was harmless include prejudice or surprise to a party against whom evidence is offered, the ability to cure the prejudice, likelihood of disruption to trial, and bad faith.” *D & D Assoc., Inc.*, 2006 WL 1644742, at *4 (citing *In re Mercedes-Benz Anti-trust Litig.*, 225 F.R.D. 498, 505 (D.N.J. 2005)). Here, where the language in CMO 4A sets forth deadlines by which each party must complete “[e]xpert discovery on general causation,” reasonable people cannot differ as to whether Plaintiffs were required to comply with the Court’s deadlines for disclosure of general causation experts set forth in CMO 4A.⁴ *See* Confoy Dec. Exh. 2, CMO 4A ¶ 4(A).

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4. Courts in this circuit have consistently excluded expert testimony for failure to comply with disclosure requirements. *See, e.g., Roberts v. United States*, CIV.A. 09-6212 WJM, 2012 WL 2374656, at *5 (D.N.J. June 22, 2012) (excluding expert testimony where “[a]llowing additional witnesses (who could have been disclosed long ago) would require” defendants to spend additional time and resources on the trial, noting that permitting newly designated experts without limitation would create “an untenable situation for opposing counsel preparing for trial”) (internal citations omitted); *Bouder v. Prudential Fin., Inc.*, CIV.A.06-4359(DMC), 2010 WL 2026707, at *5 (D.N.J. May 21, 2010) (granting defendant’s motion to strike report and preclude testimony of plaintiffs’ expert where expert was not timely disclosed); *Exxon Corp. v. Halcon Shipping Co., Ltd.*, 156 F.R.D. 589, 591-92 (D.N.J. 1994) (upholding exclusion of expert in liability phase of trial where the party offering the expert “failed to conform” with the court’s scheduling orders and did not provide a satisfactory explanation, noting that although “the exclusion of expert witness testimony is a drastic sanction, the Court understands the need to maintain

Plaintiffs' tardy disclosure is not substantially justified. Dr. Makuch relies on materials that were available long before the October 15, 2012 deadline and thus his general causation opinions could have been disclosed in a timely fashion. In fact, Dr. Makuch discusses in his report the same publications relied upon by other general causation experts disclosed in October 2012 (although Dr. Makuch performs different analyses of these publications than Plaintiffs' other experts). Thus, there is no credible explanation for why Plaintiffs waited six months after the deadline to disclose Dr. Makuch's general causation opinions.

Nor is Plaintiff's long-delayed disclosure of Dr. Makuch harmless. In his report, Dr. Makuch specifically comments upon and attempts to rebut opinions offered by one of Merck's general causation experts, Dr. Stephen Kimmel. *See, e.g.,* Confoy Dec. Exh. 6, Makuch Report at 22 ("This careful assessment refutes the remarks of Dr. Stephen Kimmel in his expert report . . ."); *id.* at 31 ("Dr. Stephen Kimmel is incorrect in several statements contained within his expert report"). The Court's CMOs do not contemplate rebuttal reports by Plaintiffs nor are such rebuttal reports expressly authorized under the Federal Rules. Plaintiffs'

control over the discovery process," "the parties are entitled to some certainty as to their preparation for trial, and if newly designated experts ... [are] permitted to enter upon the scene without limitation the need for discovery could be endless") (citations and quotation marks omitted); *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 2007 WL 979854, at * 12 n. 12 (D.N.J. Mar. 30, 2007) (granting motion to strike introduction of supplemental expert report and new affidavit from expert after expert discovery deadline had passed).

attempt at bestowing upon themselves the right to rebuttal expert reports should not be allowed.

Merck is prejudiced in other ways, too. In these Early Trial Cases, which were scheduled for trial closely together, Merck already responded to and deposed Plaintiff's initial general causation experts, Drs. Klein and Cornell, and further has cross-examined Dr. Cornell in the *Glynn* trial. Plaintiffs have the benefit of seeing Merck's attacks on Plaintiffs' general causation theory of the case and are now attempting to navigate around those attacks. In essence, Plaintiffs are asking this Court for a mulligan – plainly dissatisfied with the admissions Drs. Klein and Cornell gave in their depositions, Plaintiffs want a do-over and to try out a new general cause expert. Of course this time that new general cause expert will have had the opportunity to review and respond to Merck's experts and Merck's cross-examination of Plaintiffs' other general causation experts. CMO 4 did not set forth a process by which Plaintiffs in the Early Trial Cases have several opportunities to audition and then settle on general causation experts after Merck has disclosed its experts for those cases. In these circumstances, such a do-over does violence to the very set-up contemplated by this bellwether process, where four cases with certain commonalities -- and differences -- are to be tried in quick succession on a shared discovery schedule.

CONCLUSION

Because Plaintiffs failed to timely disclose Dr. Makuch and such failure is neither substantially justified nor harmless, Merck respectfully requests that the Court strike Dr. Makuch from Plaintiffs' *Zessin* Rule 26(a) disclosure and exclude his testimony and any references to his opinions from being introduced at trial.

Respectfully submitted,

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